

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE U.S. PATENT NO. 7,557,105

GRANTED JULY 7, 2009

FOR: N-OXIDES OF N-PHENYL-2-PYRIMIDINE-AMINE DERIVATIVES

MS: Patent Ext.

Commissioner for Patents

PO Box 1450

Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT-POST-GRANT

Sir:

This Application for Patent Term Adjustment is timely filed within two months of the issuance of U.S. Patent No. 7,557,105 on July 7, 2009.

I. Fee

As required by 37 C.F.R. § 1.705(b)(1) and (d), please charge Deposit Account No. 19-0314 for \$ 200.00 to cover the required fee (as defined in 37 C.F.R. § 1.18(e)). Please charge any deficiencies or any additional fees due in response to this request to Deposit Account 19-0314.

II. Statement of the Facts Involved

A. Correct Patent Term Adjustment

U.S. Patent No. 7,557,105 issued on July 7, 2009, indicating a patent term adjustment of 330 days.

Patentee has calculated a patent term adjustment of 360 days under 35 U.S.C. §154(b)(1)(B) or 748 days under the Wyeth v. Dudas decision based on the following facts:

1. 360 Day PTA

- (a) This patent is based on a filing under 35 USC 371 of PCT application PCT/EP03/00613.
- (b) The Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) Concerning a Filing Under 35 USC §371 (Form PTO-1390-MOD) was mailed by Express Mail with an appropriate certification on July 22, 2004. Thus, July 22, 2004 is the actual filing date of the application from which U.S. Patent No. 7,557,105 issued, and the application was pending for three years as of July 22, 2007. Patentee notes that April 29, 2006, the 371(c) date, appears on the patent term adjustment calculation found on Public PAIR, a copy of which is attached.
- (c) The 35 U.S.C. §154(b)(1)(B) period began on July 22, 2007, and ended with the issuance of the patent on July 7, 2009: a period of 538 days.
- (d) Applicant delay during prosecution totaling 178 days occurred after July 22, 2007. This delay is based on:
 - (i) an 86 day delay when responding on May 15, 2008, to the Non-Final Rejection mailed November 19, 2007; and
 - (ii) a 92 day delay when filing a Notice of Appeal on February 11, 2009, in response to the Final Rejection mailed on August 11, 2008.
- (e) Thus, in accordance with 35 U.S.C. § 154(b)(1)(B), this patent is entitled to a patent term adjustment of 360 days.

2. 748 Day PTA

(a) In Wyeth v. Dudas, 2008 U.S. Dist. LEXIS 76063 (D.D.C. 2008), the District Court of the District of Columbia addressed the United States Patent and Trademark Office (USPTO) interpretation of 35 U.S.C. §154(b)(2). The Court granted summary judgment in favor of Wyeth, determining that the USPTO misconstrued the first sentence of 35 U.S.C. §154(b)(2)(A), and as a result, improperly denied Wyeth a portion of patent term to which Wyeth was entitled under 35 U.S.C. §154.

In the opinion, the Court stated that "the PTO's view is that any administrative delay under §154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for 'A delay' or for 'B delay,' whichever is larger, but never A + B." However, Plaintiff Wyeth argued that the §154(b)(1)(A) and §154(b)(1)(B) period overlap only if they occur on the same calendar day or days. The Court determined that Wyeth's construction of § 154(b)(2) was correct.

Simply put, the holding of the Court is that the excluded overlap recited in the first sentence of 35 U.S.C. §154(b)(2)(A) only occurs if a 35 U.S.C. §154(b)(1)(A) period and a 35 U.S.C. §154(b)(1)(B) period run concurrently. As such, a patent holder is entitled to recoup the 35 U.S.C. §154(b)(1)(A) period that falls outside of the 35 U.S.C. §154(b)(1)(B) period in addition to the 35 U.S.C. § 154(b)(1)(B) period itself.

(b) For the reasons discussed above, the period under 35 U.S.C. §154(b)(1)(B) is 538 days.

(c) The 35 U.S.C. §154(b)(1)(A) period begins June 29, 2006, the date that is fourteen months after the 371(c) date, and ends on November 19, 2007, the mailing date of the Non-Final Rejection: a period of 508 days.

(d) Under Wyeth v. Dudas, total PTO delay is the sum of the delays under 35 U.S.C. §154(b)(1)(A) and (B), which is 538 days plus 508 days for a total of 1046 days.

(e) The during the period from July 22, 2007 to November 19, 2007, the delays under 35 U.S.C. §154(b)(1)(A) and (B) fall on the same calendar days. The sum of the delays is adjusted in accordance with 35 U.S.C. §154(b)(2)(A) by subtracting this 120 day period, making the total PTO delay 926 days.

(f) The 926 days is further adjusted by subtracting 178 days for the Applicant delays set forth in paragraph 1(d) above.

(g) Thus, the PTA calculated based on the Wyeth v. Dudas ruling is 748 days.

Patentee requests for the PTA to be corrected to 748 days in accordance with the Wyeth v. Dudas decision for the reasons set forth in section A (2) above. Patentee understands that the ruling in Wyeth v. Dudas has been appealed. Therefore, alternatively, Patentee requests for the PTA to be corrected to 360 days for the reasons set forth in section A (1) above in the event that the district court decision is reversed on appeal. In the event that the district court decision is modified on appeal in a manner that provides for a different PTA, Patentee requests for the PTA to be adjusted in accordance with the court decision.

B. Terminal Disclaimer

The above-identified patent is not subject to a Terminal Disclaimer.

C. Reasonable Efforts

Any applicant delays under 37 C.F.R. §1.704 are set forth above. There were no other circumstances constituting a failure to engage in reasonable efforts to conclude processing of examination of the above-identified application, as set forth in 37 C.F.R. §1.704.

Respectfully submitted,



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Date: September 3, 2009